Reports of Bleeding and Thrombocytopenia reported to VAERS after Moderna and Pfizer Covid-19 Vaccinations, 15 December, 2020 to 12 March, 2021

Reports of Bleeding and Thrombocytopenia following vaccination for COVID-19

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Abstract: Thrombocytopenia has been reported following inoculation with mRNA technology COVID vaccines. The VAERS (Vaccine Adverse Event Reporting System) database was reviewed for cases of overt thrombocytopenia and for bleeding problems--considering these may represent a less severe form of the same process. Using search words chosen to find such cases, entered between 15 December, 2020 and 12 March 2021, 358 records were retrieved and analyzed. 104 cases of thrombocytopenia were recorded, 90 severe. When documented, the majority of cases in the severe category had platelet counts below 3000. Focal and multifocal brain bleeds were reported 37 times--many fatal. Even lesser bleeding problems such as nosebleeds were unusual in their presentation. A review of this data suggests a problem with COVID mRNA vaccination involving platelets that may manifest in a variety of ways. Physicians are cautioned to be aware of this potential problem, to check blood counts in any bleeding issue however minor in conjunction to this vaccination, and to carefully document in VAERS any bleeding problem occurring within a few weeks of vaccination.

Background: Vaccination with novel mRNA technology began in mid-December, 2020. In January of 2021, a 56-year-old Florida physician was hospitalized with severe thrombocytopenia, three days after receiving the first dose of the Pfizer vaccine. In spite of being treated by a team of physicians, he died two weeks later from a brain hemorrhage, and was reported to have had no platelets. By Feb 10, 2021, 36 other similar cases were reported in the mainstream media.[1] VAERS (Vaccine Adverse Event Reporting System) is an open-source searchable data base of possible vaccine side effects reported by both providers and patients. According to the CDC website [2]:

> VAERS is used to detect possible safety problems--called “signals”--that may be related to vaccination. If a vaccine safety signal is identified through VAERS, scientists may conduct further studies to find out if the signal represents an actual risk.

The main goals of VAERS are to:

- Detect new, unusual, or rare adverse events that happen after vaccination.
- Monitor increases in known side effects, like arm soreness where a shot was given
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Asses the safety of newly licensed vaccines
- Watch for unexpected or unusual patterns in adverse event reports
- Serve as a monitoring system in public health emergencies

The CDC acknowledges limitations of the system, including:

- Reports submitted to VAERS often lack details and sometimes contain errors.
- Serious adverse events are more likely to be reported than mild side effects.
- It is generally not possible to find out from VAERS data if a vaccine caused the adverse event.

ITP or "Idiopathic Thrombocytopenic Purpura" of rapid onset most commonly effects children, and generally follows a viral illness. Only 10% of ITP cases occur in adults, who usually present with an indolent form of the disorder, referred to as chronic ITP. [3] Based on the news reports of rapid onset thrombocytopenia and death in an adult population, and the seeming inability in some cases to provide even short-term successful support through the administration of platelets, use of steroids, etc., the cases reported by mainstream media seem to fit the CDC's description of an "unexpected or unusual pattern". The VAERS data was therefore reviewed to determine if such a pattern exists, and to make some preliminary estimate of the frequency of this occurrence and to look for bleeding problems that may be related.

Methods: The VAERS database was searched using the following key words to identify potential platelet dyscrasia and bleeding problems: platelets, bleeding, hemorrhage, ITP, thrombocytopenia, thrombocytopaenia, bleed, hemorrhagic, spotting, epistaxis, hematuria, stroke, bruise, purpura, hemoptysis, hematuria, pancytopenia, hematologic, and haemotologic. In order to limit the study to products utilizing mRNA technology in general use in the United States for the period of 15 December, 2020 to 12 March, 2021, the field was further narrowed to search only for Pfizer and Moderna manufacturers. Cases were then individually evaluated by the author (a physician), categorizing them into diagnostic groups such as "multifocal brain hemorrhage", "subconjunctival hemorrhage",

"hematuria", etc. When mentioned, "Thrombocytopenia" was used as the primary diagnosis, and these cases were divided into three subcategories:

1) Severe Thrombocytopenia was chosen for cases where Thrombocytopenia was named and the patient either died, required hospitalization, suffered serious bleeding such as brain bleed, "uncontrolled hemorrhage", or in cases of very low platelet counts. (In this category all mentioned platelet counts were less than 3000).

2) Mild Thrombocytopenia in cases where no hospitalization or serious sequelae were identified, or if platelet count was noted above 50,000, and/or clear resolution was reported.

3) Thrombocytopenic rash/ bruising/ petechiae in the absence of any other information regarding platelet count.

The ages and sex of the patients were recorded in the majority of cases, and otherwise were listed as unknown age, unknown sex or both. Cases that were retrieved from VAERS using the key words but did not report bleeding or hematologic disorder were excluded. Cases which did not provide enough information to categorize or understand the incident were excluded. In cases where a patient had a diagnosis of thrombocytopenia and significant bleeding (such as a focal brain bleed) this was recorded only as thrombocytopenia, since the platelet issue was likely the probable cause of any secondary bleeding effects.

Results: There were 370 entries retrieved using the search terms above. Five cases were excluded for lack of information to clearly define the issue, and seven were excluded because the cases did not meet inclusion criteria of hematopoietic disorder or bleeding. The remaining 358 entries are listed in table 1.

Table 1. Cases Retrieved from VAERS

Severe Thrombocytopenia	94	Various Spontaneous Skin bleeding	10
Mild Thrombocytopenia	11	Vein bleeding from temple	1
Thrombocytopenic Petechial rash/bruising	5	Prolonged surgical site bleeding	3
Severe Pancytopenia	2	Severe multifocal bleeding	5
Unknown Hematologic Problem	1	Severe internal bleeding	5
Multifocal or "massive" brain hemorrhage	20	Severe uncharacterized bleeding	3

Focal brain hemorrhage	29	Bleeding from cancer site liver	1
GI Bleed	34	Renal dialysis shunt	1
Severe Vaginal Bleeding	7	Hematuria	2
Vaginal Bleeding	21	Renal bleed	1
Bleeding in Pregnancy	6	Tonsillar bleed	1
Bleeding with Miscarriage	12	Acute Uterine Fibroid hemorrhage	1
Irreg Menses	4	Nosebleed	32
Oral bleeding	8	Spontaneous Splenic hemorrhage	1
Subconjunctival Hemorrhage	11	Injection Site Bleeding	21
Intraocular bleed	4	Arm Bruising	1

Most notably there were 104 cases of Thrombocytopenia-- 90 severe, 11 mild, and three cases of petechial rash/ bruising (only). Four cases included in the severe category had low platelets in the setting of other broader hematologic disorders--two cases of pancytopenia, a case of Burkitt's lymphoma, and a myeloid leukemia--all diagnosed at the time of the report. Four thrombocytopenia cases were in young people ages 18-29--one male, one female in the severe group, and two women in the group only reporting a petechial rash or multifocal bruising . Where the sex was known, 49 patients were female, 55 were male. The ages of patients with severe thrombocytopenia are listed in Table 2.

Table 2. Ages of Patients with Severe Thrombocytopenia

Age range	Number Cases
18-29	2
30-39	9
40-49	5
50-59	31
60-64	2
65+	38
Unknown ages	3

In 29 reports, the platelet count was documented. Only 6 of these patients had platelets more than 15,000, range 28,000-114,000. Excluding those, the average platelet count for the remaining 23 records was 2,521. One patient was recorded as having "0 platelets", and another as "1 platelet". (See the full documentation by the physician below.)

49 people were reported having brain hemorrhage--29 focal, 20 massive or multifocal. 25 were female, 24 male. Six of the multifocal bleeds were registered as deaths. Three of

the focal bleeds were recorded as deaths. 15 of the cases of brain hemorrhage involved people 59 y.o. or younger.

Of the 36 GI bleeds, 21 were 60 years or older, 17 female, 29 male.

The 28 cases of vaginal bleeding in non-pregnant women, seven “severe”, were often accompanied by systemic symptoms-- dizziness, blurred vision, lymph node swelling, welts.

36 people reported nose bleeds--six were either intractable, recurrent, or recorded as having significant blood loss, or “profuse”. Associated symptoms included: photophobia, headache, hives, ”sick in bed”, brain fog, face swelling. The youngest nosebleed was in a 1-2 y.o. requiring emergency care.

Unusual skin bleeding was reported-- spontaneous bleeding from the legs, one from the scalp, one from an old biopsy site, and one from an old healed “boil” site.

Four women presented with “multifocal bleeding”, three of them with other systemic symptoms including “cough, headache, fever, nausea, diarrhea”, “cough, headache, vomiting required ambulance”, and “severe headache, hematomas on legs, 103 temperature, swollen lymph nodes”.

Prolonged post-surgical bleeding was reported. A 40-49 year-old female after an appendectomy developed prolonged bleeding necessitating reoperation 12 days later. One patient died after a CABG with prolonged post-operative bleeding. Another physician reported refractory bleeding after multiple skin biopsies, in a recently vaccinated person.

Several people clearly had such spontaneous severe bleeding problems they died before further characterization was possible.

Frank bleeding at the inoculation site occurred 14 times. Some bleeding was momentary, but often the bleeding was difficult to stop, recurrent, and/or persisted after the patient returned home.

Discussion: Thalidomide is perhaps the most famous example of a pharmacologic disaster. The drug was first was released in 1957 for its sedative effects and was touted as being safe for everyone including pregnant women and children. In 1961, Obstetrician Dr. William McBride recognized its effectiveness for “morning sickness” in pregnant women. Subsequently, he began seeing unusual birth defects in babies born to women for whom

he had prescribed the drug.[4] Independently, Dr. Widuking Lenz, a Pediatrician in Germany associated Thalidomide with severe and unusual birth defects. [5] By 1962 the drug was taken off the market.

Recognition of Thalidomide teratogenicity was made easier by several factors. First among these was the very unusual presentation of the deformities--hypoplasia or total absence of one or more extremities. Secondly, the physician who first began using the drug for nausea in pregnancy was also the doctor who delivered the affected babies. Thirdly, Dr. Lenz presciently recognized that many less severe deformities, when put into perspective, revealed "gradations of the defect and the biological limits of the syndrome are wider than at first suspected." [5]

The thrombocytopenia reported in the VAERS has features suggesting a different disorder than that encountered in classic Idiopathic Thrombocytopenia Purpura--specifically, the ages and sexes involved, the rapid onset and rapid course to death which is sometimes refractory to treatment.

Unlike in the case of Thalidomide, the lesser degrees of this problem are not easily recognized being nearly indistinguishable from bleeding issues frequently encountered in an Emergency Room or doctor's office. For example, a 75-year-old hypertensive male who suffers a brain hemorrhage and dies is not unusual, and the temporal relationship to vaccination may not be explored. Nevertheless, there are unusual features as documented above to which physicians should be alert.

Simply reviewing the numbers of reported deaths and various effects is inadequate. Experts in the field of hematology should take the time to read the reports generated by the search terms above. Here are some examples reproduced as written in the VAERS:

18-29 y.o. Female: Patient was seen in in my office on 1/19/21 with complaint of heavy vaginal bleeding. A CBC was obtained which revealed an H/H of 12.2/36.1 and a platelet count of 1 (not 1K, but 1 platelet!) This was confirmed on smear review.

39 y.o. Female: Internal brain bleeding 10 days after 1st dose Covid vaccine; brain damage, confused, suffering memory loss; This is a spontaneous report from a contactable physician (patient).

30-39 y.o. Female: 48 hours after injection developed micro-hemorrhages in her right eye. Symptoms resolved and 12/29 recurrence of bleeding to right eye slightly worse than before.

65+ y.o. Male: Patient developed significant nose bleed after receiving vaccine. Required emergency department visits x 2 and hospitalization.

65+ y.o. Female: Vaccine administered 02/02/2021. By Thursday 2/11/2021 patient almost nonverbal, by Monday 2/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as thrombocytopenia. Deceased by Friday, 2/19/20201.

Unknown age female: Same day after getting the shot I developed chills. I came home from work and I took a shower and went to bed. Next day I woke up with nausea and headache. Later that day I had a nose bleed. The following day I was so weak, tired and dark urine.

40-49 y.o. Female: Bleeding, myalgia, tingling in the fingers of the right hand; fatigue immediately upon vaccination--bleeding at the injection site which the employee reports as filling the Band-Aid over the site. When she got home in the evening and took it off blood ran.

Conclusion: Complications from any new medication are difficult to pick up very early in the "roll out" due to the infrequency of the occurrences, and the geographical separation between cases. In the case of the Thalidomide, it was very helpful that the prescribing Obstetricians also witnessed the complications. That is rarely true in the case of vaccinations, especially where the patient needs no physician to obtain a vaccine. Furthermore, serious complications present to Emergency Departments not in a physician's office where he/she could get a sense or what was happening.

VAERS has the potential to shorten recognition time by trying to spot the "unusual patterns" as recommended by the CDC VAERS program itself. But, this requires that physicians be aware of the system, and take the time to enter any suspected side effect--not just the worst cases. A report previously submitted to the Agency for Healthcare Research and Quality revealed that fewer than 1% of adverse events get reported to VAERS. [6]

The Moderna and Pfizer COVID-19 vaccines employ a mode of vaccination never before used on humans. In previous animal studies, animals succumbed to what was then called "Immune Enhancement"--now referred to as "Antibody Dependent Enhancement". [7] Problems specifically involving the clotting system, including antibody mediated platelet damage, have also been reported, and caution advised by past researchers.[8] [9] [10] Cases of thrombocytopenia by themselves may be considered so rare as to be very low risk. But, as in the case of Thalidomide where Dr. Lenz recognized the gradient of presentation, this review suggests that overt thrombocytopenia is just one manifestation of a larger

spectrum of disorders ranging from injection site bleeding to overt thrombocytopenia. It is incumbent upon physicians who recommend these experimental agents to follow their patients, become familiar with VAERS to document any problems, and employ the precautionary principle.

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